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| 10/036,235      | 12/27/2001  | James Thomas         | 45774/JWP/T469      | 3357             |

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EXAMINER

ROBERT, EDUARDO C

ART UNIT PAPER NUMBER

3732

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/036,235

Applicant(s)

THOMAS, JAMES

Examiner

Eduardo C. Robert

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,9,12,18,21-23,26,31,33 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,8,10,11,13-17,19,20,24,25,27-30 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/27/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 3732

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election of Invention I (claims 1-30, 32, and 33) and Species IV (Figures 5a-5d) in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without traverse** (MPEP § 818.03(a)).

It is acknowledged that applicant believes claims 1-4, 7, 8, 10, 11, 13-17, 19, 20, 24, 25, 27-30, and 32 read on the elected Species IV and that claims 1-3, 7, 8, 11, 13, 14, 16, 17, 20, 24, 25, 27-30, and 32 are generic claims. The examiner agrees with applicant.

Claims 5, 6, 9, 12, 18, 21-23, 26, 31, 33 and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention and/or species, there being no allowable generic or linking claim. Election was made **without traverse** in Paper No. 7.

### *Oath/Declaration*

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the citizenship of each inventor.

Art Unit: 3732

### ***Drawings***

The drawings are objected to because Figure 10 appears to contain 2 separate figures, and thus each figure should be labeled separately, e.g. Figure 10A, Figure 10B. Also, each of Figures 12-14 has the same problem of Figure 10, and thus they should be fixed in a similar manner. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Applicant is required to submit a proposed drawing correction in response to this Office Action. Any proposal by the applicant for amendment of the drawings to cure defects must consist of two parts:

- a) A separate letter to the Draftsman in accordance with MPEP § 608.02(r); and
- b) A print or pen-and-ink sketch showing changes in red ink in accordance with MPEP § 608.02(v).

**IMPORTANT NOTE:** The filing of new formal drawings to correct the noted defect may be deferred until the application is allowed by the examiner, but the print or pen-and-ink sketch with proposed corrections shown in red ink is required in response to this Office Action, and may not be deferred.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 7, 8, 10, 11, 13-17, 19, 20, 24, 25, 27-30, and 32 are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 4 and 5, respectively, “the proximal end of the shaft” and “the distal end of the shaft” each lacks a prior antecedent. Also, in lines 11 and 13, respectively, “the distal end of the shaft” and “the proximal end of the shaft” each lacks a prior antecedent.

Art Unit: 3732

There exists an inconsistency between the language of claim 7 and that of the claim 8 dependent thereon, thus making the scope of the claims unclear. In claim 7 applicant recites “A vertebral alignment assembly” with the threaded attachment being only functionally recited, i.e. “to receive a threaded attachment”, thus indicating that the claim is directed to the subcombination, “A vertebral alignment assembly”. However, in claim 8 applicant positively recites the threaded attachment as part of the invention, i.e. “wherein the threaded attachment is either a T-type handle or a screwdriver-type handle”, thus indicating that the combination, vertebral alignment assembly and threaded attachment, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes the claims will be considered as being drawn to the subcombination, alignment assembly.

There exists an inconsistency between the language of claim 1 and that of the claim 11 dependent thereon, thus making the scope of the claims unclear. In claim 1 applicant recites “A vertebral alignment assembly” with the attachment hardware being only functionally recited, i.e. “for attachment of at least one piece of fixation attachment hardware”, thus indicating that the claim is directed to the subcombination, “A vertebral alignment assembly”. However, in claim 11 applicant positively recites the attachment hardware as part of the invention, i.e. “wherein the fixation attachment hardware is chosen from the group consisting of: ...”, thus indicating that the combination, vertebral alignment assembly and attachment hardware, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination.

Art Unit: 3732

Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes the claims will be considered as being drawn to the subcombination, alignment assembly.

In claim 14, lines 6 and 7, respectively, “the proximal end of the shaft” and “the distal end of the shaft” each lacks a prior antecedent. Also, in lines 12 and 14, respectively, “the distal end of the shaft” and “the proximal end of the shaft” each lacks a prior antecedent.

Claims 24 and 25 have a problem similar to the one of claims 7 and 8, discussed above. Claims 24 and 25 have been treated in the same manner as claims 7 and 8.

In claim 28, line 4, “inserting an alignment rod” is indefinite because it is unclear if this “alignment rod” is the same from parent claim 14 or another one in addition to the one recited in parent claim 14.

In claim 32, lines 4-6, respectively, “the proximal end of the anchor body”, “the distal end of the anchor means”, and “the proximal end of the shaft” each lacks a prior antecedent. Also, in lines 10 and 12, respectively, “the distal end of the shaft” and “the proximal end of the shaft” each lacks a prior antecedent.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3732

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7, 8, 11, and 32, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Winslow et al. (Reference U.S. Patent 5,885,299 cited on IDS by applicant).

Winslow et al. disclose an assembly comprising an implant with threads or screw 200, having an elongated, partially cannulated shaft defining an axially arranged inner screw chamber that includes bore 216, an screw axis, and an axial opening 218 at a proximal end of the screw which provides access to the inner screw chamber (see Figures 6 and 7). The screw has a tapered tip 204 (see Figure 8A). A proximal end of the screw has an anchor mechanism, e.g. indentations 220 and 222, for engaging clamps 116. The assembly also comprises a rod including an elongated shaft 132 with an engaging portion 144 arranged at a distal end of the shaft design to insert into the axial opening 218 and cooperatively engage the inner screw chamber, e.g. bore 216. The rod further comprises an elongated portion at a proximal end having an outer diameter less than that of the screw, e.g. section 132 shown in Figure 9B. The bore 216 includes threads that cooperate with threads of engaging portion 144. The elongated portion of the rod is threaded (see Figure 2).

Claims 1, 2, 10, 11, and 32, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Howell et al. (U.S. Patent 5,674,224).

Howell et al. disclose an assembly comprising a screw 42, having an elongated, partially cannulated shaft defining an axially arranged inner screw chamber, an screw axis, and an axial opening at a proximal end of the screw which provides access to the inner screw chamber (see Figure 2). The screw has a tapered tip (see Figures 2 and 3). A proximal end of the screw has an

Art Unit: 3732

anchor mechanism, e.g. threads on outer surface. The assembly also comprises a rod including an elongated shaft 126 with an engaging portion arranged at a distal end of the shaft design to insert into the axial opening and cooperatively engage the inner screw chamber (see Figures 11 and 12). The rod further comprises an elongated portion at a proximal end having an outer diameter less than that of the screw (see Figures 11 and 12). The assembly further comprises a filler plug 44 mateable with inner screw chamber. The plug lockingly engage within and fill the inner screw chamber.

Claims 1-4, 7, 8, 11, and 32, as understood, are rejected under 35 U.S.C. 102(e) as being anticipated by Huene (Reference U.S. Patent 6,077,267 cited on IDS by applicant).

Huene discloses an assembly comprising a screw, e.g. S1, having an elongated, partially cannulated shaft defining an axially arranged inner screw chamber, an screw axis, and an axial opening at a proximal end of the screw which provides access to the inner screw chamber (see Figure 2). The screw has a tapered tip (see Figures 3 and 6). A proximal end of the screw has an anchor mechanism, e.g. 24 or 68. The assembly also comprises a rod 28 including an elongated shaft with an engaging portion arranged at a distal end of the shaft design to insert into the axial opening and cooperatively engage the inner screw chamber (see Figure 2). The rod further comprises an elongated portion at a proximal end having an outer diameter less than that of the screw (see Figure 1). The screw chamber includes threads that cooperate with threads of engaging portion (see Figure 2). The elongated portion of the rod is threaded at 46.



***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winslow et al.

Winslow et al. disclose the claimed invention except for the assembly being made from stainless steel or titanium. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Winslow et al. from stainless steel or titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

***Allowable Subject Matter***

Claim 30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 14-17, 19, 20, 24, 25, and 27-29 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Art Unit: 3732

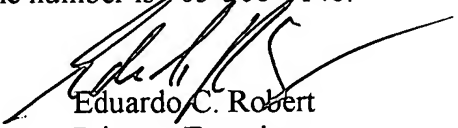
*Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited art of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Eduardo C. Robert  
Primary Examiner  
Art Unit 3732

E.C.R.